510(k) Summary for the

Dimension® Clinical Chemistry System Lipase Calibrator

(LIPL CAL – DC56)

AUG - 4 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

May 8, 2008

A. 510(k) Number: K081319

B. Analyte: Lipase

C. Type of Test: Calibrator Material

D. Applicant:

Siemens Healthcare Diagnostics Inc, P.O. Box 6101, Newark, DE 19714-6101

Victor M. Carrio, Regulatory Affairs and Compliance Manager

Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension® Clinical Chemistry System Lipase Calibrator

(LIPL CAL – DC56)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator

2. Classification: Class II

3. Product Code: JIT – Secondary Calibrator

4. Panel: Clinical Chemistry

G. Standard/Guidance Document Referenced:

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final,02/22/1999

ISO 14971:2007 Medical devices -Application of risk management to medical devices

H. Intended Use:

The LIPL Calibrator is an in vitro diagnostic product to be used to calibrate the Lipase (LIPL) method for the Dimension® clinical chemistry systems.

I. Device Description:

The LIPL calibrator is a liquid bovine serum albumin-based product. The level 1 calibrator contains no detectable lipase. Levels 2 and 3 contain porcine pancreas lipase. The kit consists of six vials, two vials of Calibrator Level 1, two vials of Calibrator Level 2,

and two vials of Calibrator Level 3 which are ready for use (no preparation is required). The volume per vial is 1.0 mL.

J. Substantial Equivalence Information:

The Dimension® Clinical Chemistry System Lipase Calibrator (DC56) and the predicate device, the Dimension Vista® Enzyme 1 Calibrator were compared. The following table provides a comparison of the important similarities and differences between the device and the predicate:

	Device	Predicate Device
Item	**Dimension® clinical chemistry system Liquid Lipase calibrator**	**Dimension Vista® System Enzyme 1 Calibrator**
Intended Use	The LIPL Calibrator is an in vitro diagnostic product to be used to calibrate the Lipase (LIPL) method for the Dimension® clinical chemistry systems.	The Vista® System Enzyme 1 Calibrator is an *in vitro* diagnostic product for the calibration of Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE) methods on the Dimension Vista® System.
Analytes	Lipase	Amylase, Gamma-Glutamyl Transferase, Lactate Dehydrogenase, Lipase, and Pseudocholinesterase
Form	Liquid	Liquid
Traceability	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.
Matrix	Bovine serum base with Lipase (porcine pancreas).	Bovine serum base with amylase (human saliva), GGT (bovine kidney), LDH (chicken heart), lipase (porcine pancreas), and PCHE (horse serum).
Number of Levels	Three (3) levels.	Two (2) levels.

K. Performance Characteristics:

Traceability: The assigned values of the Dimension® LIPL Calibrator are traceable to Master Pool values, assigned on the Dimension® clinical chemistry system.

Master Pool level 1 of BSA base is assigned a value of 0 U/L. LIPL Master Pool bottle values levels 2 and 3 are assigned on multiple instruments calibrated with LIPL Anchor Pool. The LIPL Anchor Pool values are assigned using an external reference system (PBS/Precical®). A previous Master Pool lot is used as a control.
Calibrators are prepared gravimetrically from porcine lipase. The concentration of each level is verified against Master Pool

values.	
File Attachment	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 4 2008

Siemens Healthcare Diagnostics Inc.
c/o Mr. Victor M. Carrio
Senior Manager of Regulatory Affairs
P.O. Box 6101, Mailbox 514
Newark, DE 10714-6101

Re: k081319
Trade Name: Dimension® Lipase Calibrator (DC56)
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 11, 2008
Received: July 14, 2008

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081319

Device Name:

Dimension® Lipase Calibrator (DC56)

Indication For Use:

The LIPL Calibrator is an in vitro diagnostic product to be used to calibrate the Lipase (LIPL) method for the Dimension® clinical chemistry systems.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081319